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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,079	07/19/2002	Jitao Zou	83815-3002	2764

7590 06/17/2005
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CANADA

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,079

Applicant(s)

ZOU ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 4-6, 13-15, 22-24 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/19/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Art Unit: 1638

DETAILED ACTION

The amendment filed March 17, 2005 has been entered.

Claims 40 and 41 are newly submitted.

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on March 17, 2005 is acknowledged.

Claims 1-38, 40 and 41 are drawn to the elected invention and are examined on the merits.

Claim 39 is withdrawn as drawn to a non-elected invention.

Drawings

Figures 5, 7 and 8 are objected to because they are not legible.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10, 19 and 29, and claims 2, 3, 7-9, 11, 12, 16-18, 20, 21, 25-28, 30, 31, 35-38, 40 and 41 dependent thereon, are indefinite in the recitation of "a heterologous glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than wild type glycerol-3-phosphate dehydrogenase", given that it is unclear what would constitute the wild type enzyme,

Art Unit: 1638

so therefore it is unclear what a glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition would be.

Claims 3, 12, 21 and 31 are indefinite in the recitation of “gpsA2^{FR}”, since this name does not identify what is claimed. If this is the same as SEQ ID NO: 2, then that should be indicated in the claim.

Claim 7, 16, 25 and 35 are indefinite in the recitation of “oilseed bearing plant”, given that the specification defines this term as plants from which oil can be isolated in marketable quantities (page 8). However, the specification does not set forth the metes and bounds of this term.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of using a glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than wild type glycerol-3-phosphate dehydrogenase and to plants transformed by that method. Claims are also drawn to use of a DNA sequence encoding said enzyme that has a single amino acid substitution that renders it feedback defective, while not significantly altering its catalytic ability, and to the

Art Unit: 1638

dehydrogenase that is gpsA2^{FR}. However, the specification only discloses DNA encoding the amino acid sequence of SEQ ID NO: 2. The specification does not describe any other sequences that would have the claimed functional activities stated above. The specification does not describe the structure that is required for the claimed functional activity.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed..

6. Claims 1-3, 7-12, 16-21, 25-31, 35-38, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using DNA encoding SEQ ID NO: 2 to transform a plant, does not reasonably provide enablement for a method of expressing in a plant any glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than wild type glycerol-3-phosphate dehydrogenase and plants transformed by that method, or to use of a DNA sequence encoding said enzyme that has a single amino acid substitution that renders it feedback defective, while not significantly altering its catalytic ability, or to gpsA2^{FR}. The specification does not enable any person skilled in the art to which it

Art Unit: 1638

pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not provide working examples of any sequence other than DNA that encodes SEQ ID NO: 2. In addition, the specification does not provide any guidance with regard to what other sequences would encode a glycerol-3-phosphate dehydrogenase that is less sensitive to feedback inhibition than wild type glycerol-3-phosphate dehydrogenase, and the specification does not provide any guidance with regard to identifying either a wild type glycerol-3-phosphate dehydrogenase or said enzyme that is less sensitive to feedback inhibition than wild type; or identifying a DNA sequence encoding said enzyme that has a single amino acid substitution that renders it feedback defective, while not significantly altering its catalytic ability, or to $gpsA2^{FR}$. And the prior art does not teach that sequences having the claimed activity were known. However, identification of a DNA sequence encoding said enzyme having the claimed activity is highly unpredictable, particularly given that it is unclear what the modified enzyme is to be compared to.

Given the high level of unpredictability with regard to identifying a sequence encoding a DNA sequence encoding said enzyme that less sensitive to feedback inhibition or has a single amino acid substitution that renders it feedback defective, while not significantly altering its catalytic ability; and given the lack of working examples of any sequences other than sequences that encode SEQ ID NO: 2; and given the absence of guidance of how to identify a sequence having the claimed activity from the multitude of possible sequences that could be the wild type sequence or variations thereof; and given the breadth of the claims and the state of the prior art; it

Art Unit: 1638

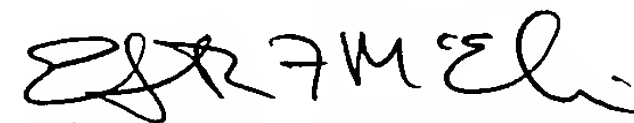
would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claims 4-6, 13-15, 22-24 and 32-34 are objected to for depending on a rejected base claim, but would be allowable if written in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM